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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,447

06/22/2005

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JAB1731f

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27777 7590 08/06/2008  
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EXAMINER

BERNHARDT, EMILY B

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

08/06/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/540,447	<b>Applicant(s)</b> JANSSENS ET AL.	
	<b>Examiner</b> EMILY BERNHARDT	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-9 and 12-18 is/are pending in the application.
- 4a) Of the above claim(s) 17 and 18 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4,6-8 and 14-16 is/are allowed.
- 6) ☒ Claim(s) 9,12 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/30/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

In view of applicants' response filed 4/30/08 the following applies.

Applicant's election of I in the reply filed on 4/30/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 9 and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 12 has been amended to recite "a method of treating " which is a statutory claim but is of indeterminate scope for the following reasons. Defining a disease(s) by its (their) underlying cause renders the scope of intended uses indeterminate since the claim language may read on diseases not yet known to be caused by or affected by such action or in ways not yet understood. Additionally, determining whether a given disease responds or not to NK antagonistic activity involves much experimentation since a negative response from one patient does not mean the drug isn't useful as no drug has 100% effectiveness. Thus what "success rate" determines if a particular compound is effective and how many patients (and dosage regimens) need to be tested? The test for determining compliance with 35 USC 112, par. two is whether applicants have clearly defined "their" invention not what may be discovered by future research as this type of claim language clearly requires.

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2. Claim 9 appears to be incomplete. On several pages (9-12) it appears a "4" is missing in front of R/S configurations. See for example 1st species on p.9, 3rd species on p.10 and all species on pages 11 and 12. Additionally, it is noted that the species are sometimes recited by way of formula and other times by way of text. If possible, semicolons should separate the species or they can be presented by sequential numbering with an "and" inserted before the last species.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is not clear where support can be found for every species newly added. For example, the t-butylcarbonyl species appearing on p.7 in claim 9 appears racemic in the formula but in Table 1 only specific stereoisomers are named. Applicants need to specifically point out by way of compound nos. where descriptive support can be found for all the species claimed.

3. Claim 13 (not present in preliminary amendment) recites "such as " which makes intended scope unclear. Is subject matter before or after the phrase being claimed?

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for uses embraced in claim 13, does not reasonably provide enablement for scope covered in the generic claim. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly

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connected, to use the invention commensurate in scope with these claims. The claim amended to treatment of tachykinin-mediated conditions from a reading of the specification (see pp.18-22), includes (but is not limited to) whole classes of disorders such as sleep, cognitive, eating, neurodegenerative, gastrointestinal, all skin and addictive disorders, all types of vasospastic diseases as well as collagen diseases, all forms of sexual dysfunction. The notion that NK-1 or NK-2 or NK-3 antagonists have such a range of uses is not remotely warranted given the current state of the art such as Sanger or Ohnmacht, provided with this action which show limited applications for treating uses in claim 13. Note Hoffman V. Klaus 9 USPQ2d 1657 regarding the standard of testing that is necessary to establish the likelihood of *in vivo* use. Also see Ex parte Powers 220 USPQ 925. Where the utility is unusual or difficult to treat or speculative, the examiner has authority to require evidence that tests relied on are reasonably predictive of *in vivo* efficacy by those skilled in the art. See for example, In re Ruskin 148 USPQ 221; Ex parte Jovanovics 211 USPQ 907.

Note also the criteria for enablement as set out in In re Wands cited in MPEP

2164.01(a), August 2000 edition which considers factors such as:

- 1) Breadth of the claims- The claims cover (but are not limited to) to a huge variety of unrelated disorders ;
- 2) Level of skill in this art- there are no drugs that are either NK-1, NK-2, NK-3 antagonists or a mixed profile of all 3 which have such a spectrum of clinical applications and thus the level of skill is low ;
- 3) State of the prior art- as far as the examiner is aware there are no compounds

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similar in structure which have been reported to be preclinically much less clinically active for such a range of uses;

4) Working examples- There are no test(s) directed to the many uses pointed out above which are art-recognized for predicting *in vivo* efficacy .

Thus in view of the above the rejection is being applied.

The objection/rejection regarding improper incorporation by reference is withdrawn as applicants have demonstrated that the reactants are otherwise enabled by the actual examples described in the specification .

Claims 1-4, 6-8 and 14-16 are allowed. It is noted a comma should follow the "Y" choice "-SO<sub>2</sub>-" on the last line of p.2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Bernhardt/  
Primary Examiner, Art Unit  
1624